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CASMED®

510(k) SUMMARY

Submitter: CAS Medical Systems, Inc.

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Prepared: January 5, 2011

Trade Name: FORE-SIGHT® Absolute Tissue Oximeter

Common Name: FORE-SIGHT Oximeter

Classification Name: Oximeter, Tissue Saturation (870.2700)

PREDICATE DEVICE

The FORE-SIGHT® Absolute Tissue Oximeter is equivalent to the following devices:

- CAS Oximeter Monitor (K094030)
- Somanetics INVOS® 5100C Oximeter (K091224)

DESCRIPTION

The FORE-SIGHT Absolute Tissue Oximeter measures a single parameter of oxygenated hemoglobin under the Sensor, allowing the clinician to continuously and accurately determine absolute levels of blood oxygenation in the tissue.

The Oximeter monitor features a LASER-SIGHT® Optical Technology generating 4 precise wavelengths to optimize measurement of targeted hemoglobin states. COOL-LIGHT™ sensor technology ensures zero risk of patient burns. 3 sizes of sensors are available. The Oximeter is for continuous or spot checking use in a variety of hospital settings. A rechargeable battery pack permits the monitor to be used independently from an AC power source.

INTENDED USE

The noninvasive FORE-SIGHT® Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

When used with Large sensors, the FORE-SIGHT Oximeter is indicated for use on the brain of adults and children over 40 Kg.

When used with Medium sensors, the FORE-SIGHT Oximeter is indicated for use on the brain of small adults and children between 4 and 80 Kg, and for use on skeletal muscle of infants, children and adolescents between 4 and 50 Kg.

When used with Small sensors, the FORE-SIGHT Oximeter is indicated for use on the brain of infants and neonates less than 8 Kg, and for use on the abdomen in neonates less than 4 Kg.

The prospective clinical value of data from the FORE-SIGHT Oximeter has not been demonstrated in disease states and these data should not be used as a sole basis for diagnosis or therapy.

FORE-SIGHT Monitor Technology Compared to Predicate Devices

The FORE-SIGHT Absolute Tissue Oximeter compares substantially to one or more of the cited predicate devices in that they use fundamentally the same optical operating principle, called diffuse reflectance spectroscopy. All cited monitors use light to examine a cross-section tissue microvasculature (a mixed bed of arterioles, capillaries and venules). The FORE-SIGHT Monitor and predicate devices analyze the light that is returned after having passed through tissues. The analysis is for hemoglobin in its oxygenated and deoxygenated states. All cited monitors calculate oxygen saturation which reflects the percentage of oxygenated hemoglobin in the sampled tissue.

The FORE-SIGHT Absolute Tissue Oximeter is identical to the FORE-SIGHT predicate, except for the software and user interface modifications to support the expanded indications.

Non-Clinical Performance Testing to Demonstrate Substantial Equivalence

The FORE-SIGHT® Absolute Tissue Oximeter has successfully undergone extensive performance, safety, electromagnetic, clinical, software and environmental testing to ensure it has been found to be substantially equivalent to the FORE-SIGHT predicate device. In addition to the above laboratory tests, CAS has conducted a full program of individual hardware, software and systems verification and validation studies of the FORE-SIGHT monitor and sensors.

Clinical Testing to Show Substantial Equivalence

The FORE-SIGHT Absolute Tissue Oximeter has successfully undergone extensive clinical study for the expanded indications for use especially for neonatal subjects. The premarket notification cites validation report "Validation of the CASMED FORE-SIGHT® Tissue Oximeter for Skeletal Muscle and Abdominal Tissue Oxygen Saturation (StO_2%) in Pediatric and Neonatal Subjects".

Conclusions Drawn from Clinical and Non-Clinical Testing

Clinical evaluation, safety testing and software validation demonstrate the FORE-SIGHT Absolute Tissue Oximeter is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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CAS Medical Systems, Inc.
c/o Mr. Ron Jeffrey
Director, Regulatory Affairs
44 East Industrial Road
Branford, CT 06405

Re: K112820
Trade/Device Name: FORE-SIGHT® Absolute Tissue Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: January 4, 2012
Received: January 9, 2012

Dear Mr. Jeffrey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah Falls

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number K112820:

Device Name: FORE-SIGHT® Absolute Tissue Oximeter

Indications for Use:

The noninvasive FORE-SIGHT® Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

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Prescription Use ___X___ AND/OR Over-The Counter Use_____

(PLEASE DO NOTR WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Dan I Kaufman MA

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K112820